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Examples of restrictions to global access to maximize impact

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CGIAR Principles on Intellectual Assets

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Examples of restrictions to global access to maximize impact

Some donors requested concrete examples illustrating how restrictions to global access through Limited Exclusivity Agreements (Article 6.2), Restricted Use Agreements (Article 6.3) and IP Applications (Article 6.4) can sometimes be necessary to maximize impact in furtherance of the CGIAR Vision.

1. Limited Exclusivity Agreements (Art. 6.2)

Limited Exclusivity Agreements are those through which the Consortium and/or the Centers agree to limited exclusivity for commercialization of intellectual assets they produce. Such agreements are permitted under the following conditions:

- the exclusivity is necessary for the further improvement of such intellectual assets or to enhance the scale or scope of impact on target beneficiaries, in furtherance of the CGIAR Vision;
- the exclusivity is as limited as possible in duration, territory and/or field of use;
- the agreements provide that the intellectual assets remain available in all countries for non-commercial research conducted by public sector organizations and in the event of a national or regional food security emergency for the duration of the emergency.

Example 1:
A Center identifies an effective, safe, biopesticide but does not have the resources (or mandate) to develop it for use by would-be beneficiaries. No other organization is willing to take over further development of the product on a non-exclusive basis.
Company X, on the other hand, is willing to further develop the biopesticide into a product suitable for use by farmers, but only on the condition that it has exclusive rights to market it *in developed countries* (geographically-limited exclusivity, an example of market segmentation). Company X is content that the product, once developed, can be commercialized by others in developing countries and that the intellectual asset remains available for research by public sector organizations in support of the CGIAR Vision.
Article 6.2 would permit the Center to conclude such an agreement with Company X because exclusivity is "*necessary for the further improvement of the Center's intellectual assets, in furtherance of the CGIAR Vision*".

Example 2:
A Center develops a promising crop variety, but does not have the resources to effectively disseminate it to farmers in developing country X. Country X's national public research and extension agencies inform the Center that they too lack the means to get the variety out to farmers. There are a few small seed companies that are interested in marketing the variety in Country X, but none of them is willing to even try unless they are granted an exclusive license to commercialize the variety in the country. In the absence of an exclusive license, the companies fear they will end-up undermining each other's ability to recoup the modest financial gains that might be available through sales in the country.
Article 6.2 would permit the Center to grant a time-limited exclusive license with a Research Exemption to a single company to commercially market the variety in the country concerned, because this would be "*necessary to enhance the scale or scope of impact on target beneficiaries, in furtherance of the CGIAR Vision*". At the same time, however, the Center would still make the variety available to public sector organizations in country X for research (including breeding) purposes. This would facilitate potentially important further uses of the variety in pursuit of developing other

improved materials. Other companies could alos 'bulk up' seeds for sale once the period of exclusivity is over.

Example 3:
The main exclusive agreement that Centers enter into is when they assign copyrights to the publisher of scientific journals. Why would a Center do this? In order to get their reports published so that they can be read by the largest audience possible. Traditional publishers in the ag development field such as CABI require this, as well as many journals that have the highest readership and impact (e.g. Science and Nature). The "Open Access" publishers are growing in number and in readership, but the ag development field seems to lag on this score (as compared to molecular biology for example).

2. Restricted Use Agreements (Art. 6.3)

Restricted Use Agreements are for the acquisition and use of third party intellectual assets. Such agreements restrict the global accessibility of the resulting products/services for commercialization, research and development. Such agreements are permitted under the following conditions:

- the Consortium and/or the Centers are, to the best of their knowledge, unable to acquire equivalent intellectual assets from other sources under no or less restrictive conditions;
- the products/services that are intended to result from the use of third party intellectual assets further the CGIAR Vision in the countries where they can be made available;
- the Consortium and/or the Centers use their best efforts to ensure that the third party intellectual assets are only used in relation to, or incorporated into, such intended products/services.

Example 1:
A Center was able to obtain a license from Company A to use an intermediate technology (sequence useful for marker-assisted selection) to select a crop variety to be released by the Center in smaller, poorer, developing countries in a region, but not the larger developing countries in the same region, not even for research purposes. In this example, the Center is in the best position to breed the new variety as it has many germplasm options available to test different crosses.
In this case, if the technology both a) contributes to food security ("*furthers the CGIAR Vision*") in the limited number of developing countries where it can be made available by the Center, and b) is not available from an alternative source under no or less restrictive conditions, Article 6.3 would allow the Center to enter into such an arrangement.

Example 2:
A Center has received a donation of elite germplasm from a private sector partner under a license that restricts global access. The Center carries out a cost/benefit analysis and determines that it will accept the donation, subject to a humanitarian use license that allows the Center to use the materials for research, breeding and dissemination in markets where the Center can reach target beneficiaries. The Center could also grant a sub-license to a seed company to disseminate the products under the same conditions (humanitarian use license).

3. IP Applications: plant variety rights or patents (Art. 6.4)

Under Article 6.4, Centers made register or apply for IP Applications (patents and/or plant variety protection) only if this is "*necessary for the further improvement of the Intellectual Assets or to enhance the scale or scope of impact on target beneficiaries, in furtherance of the CGIAR Vision*".

Example 1:
Continuing from Example 1 page 1 (biopesticide example), under Article 6.4, the Center could file for patent protection over the biopesticide *in developing countries* so the Center would be in position to

grant licenses to commercialize the product under relevant terms (e.g. preferential terms). Company X could also file for patent protection over the biopesticide *in developed countries* to prevent competitors from undermining their exclusive market position in those countries.

Example 2:
Centers do not usually seek Plant Variety Protection (PVP) or patent protection themselves on the products of their research. They do however sometimes allow others to do so with regards to products derived from Center lines (i.e. not the Center lines themselves). This would be subject to the terms of the SMTA under the International Treaty which requires payment into a fund in the event the products that are commercialized are restricted for further research and breeding. Centers view the registration by partners of varieties derived from their lines as an important means of promoting the access and benefit sharing principles of the International Treaty.

Examples showing why it is sometimes necessary for a partner to file a patent or Plant Variety Protection (PVP) :

Example 1:
Company X has intellectual assets that take the form of business information and know-how that are specific to a grain storage business. To secure financing, the business owners must demonstrate to financial investors that they have obtained secure rights over their intellectual assets (such as patent protection), in order to obtain the investment start-up funds needed to get the business going.

Example 2:
Continuing from Example 2 page 1 (varietal development), Article 6.4 would allow the company to seek Plant Variety Protection (PVP) within country X to enforce the conditions of their exclusive agreement with the Center against would-be commercial competitors (who might obtain the variety from sources other than the Center).

Examples showing why Limited Exclusive Agreements or IP Applications are sometimes needed:
Seasoned scientists that work in crop breeding have observed that if Centers continue to release materials with no protection (e.g. "freely available" as often stated in donor publications) extolling the work of Centers, exactly the opposite happens. Multinationals pick up Center technologies, traits, varieties etc. freely, package them in proprietary combinations, charge what they want ("what the market will bear") and effectively restrict access. All of this is done without any obligation to share their profits or assure access. This is not speculation and is already happening with Centers' mandate crop traits. The only way to prevent or manage this is for Centers to license materials, including traits, in a way that manages this. In addition, as National Systems are under increasing budget pressure, they are licensing to multinationals materials they receive "freely" from Centers with no benefit returning to the originating Centers. This is also already occurring.

Annex 1

CGIAR CENTER CASE STUDIES

1. Limited Exclusivity Agreements

➢ ICRISAT's Hybrid Parents Research Consortia (HPRC)

ICRISAT's HPRC programs, established in 2000, provide an example of a time-Limited Exclusivity Agreement. Private sector seed companies become members of a consortium by paying a nominal membership fee and signing a consortium agreement. Member companies participate in annual research planning meetings, contribute hybrids in ICRISAT-organized hybrid evaluation trials (on-farm and on-station), and have 3-year preferred access to the improved parental lines developed by ICRISAT, useful for the production of sorghum, pearl millet and pigeon pea hybrid seed. All ICRISAT-bred parental lines retain a Research Exemption for further research and breeding by all public sector partners. As these materials fall under the International Treaty's category of "Material Under Development", an additional Material Transfer Agreement (MTA) is applied along with the SMTA. Parental lines can be used by the private sector seed companies for making hybrids (often using one of their own proprietary parental lines) and they can register these hybrids for sale in a country.

The main objective of the HPRC is to capitalize on the private sector's expertise in marketing hybrid seed, thus making such improved hybrids available earlier than normal to farmers, while attracting private sector seed companies to support the breeding research conducted by ICRISAT. The impact of the ICRISAT-derived/private sector distributed improved pearl millet and sorghum materials, is well documented in several studies including Chapter 12[1]. Every year, an estimated US$650,000 is provided to the ICRISAT sorghum, pigeon pea and pearl millet breeding programs through the consortia[2] to support breeding research that is consistent with ICRISAT's mission, mandate and agreed research agenda.

Are these Limited Exclusivity Agreements necessary for materials to reach the small-holder farmer in India?
ICRISAT has learned that this 3-year time-limited exclusivity, where HPRC members can benefit from the sale of hybrids before non-members, is important to provide an incentive for the HPRC members to join the consortia. Without this option of Limited Exclusivity Agreements, ICRISAT would be faced with inefficient mechanisms to deliver hybrids to farmers and thus to maximize global access to these materials.

➢ ILRI's Diagnostic Test Kits for Detecting "Tick Borne Disease"

An example of a "field-of-use"- Limited Exclusivity Agreement by ILRI involved the licensing of ILRI-derived reagents to a pharmaceutical company (Sanova Biotech AB) for the purposes of producing test kits for the detection of tick borne parasites. In a "field-of-use" exclusive license, the licensed materials are still available for any other use.

In the course of vaccine work on prevention of tick borne diseases of cattle, ILRI scientists had developed many laboratory reagents that also had potential use as diagnostic tools for researchers and veterinarians. ILRI supplied materials such as antigens, hybridomas, sera, and recombinant DNA

[1] Pray and Nagarajan (2010) of the IFPRI report "Millions Fed" (available at http://www.ifpri.org/publication/millions-fed)
[2] Gowda et al. 2007

constructs under an exclusive license to the company. The company provided these reagents in a ready-to-use form to other researchers and veterinarians.

Was this Limited Exclusivity Agreement necessary for materials to reach those working with/ for small scale cattle farmers in East Africa?

ILRI is not in the "test kit" business. Sanova was. Sanova could assemble test kits and sell them much more cheaply than ILRI could make them and sell "at cost". However, Sanova needed an exclusive license over these reagents *for the purpose of making test kits* ("field-of-use" restriction) to ensure that their investment in initiating production of these kits would be profitable for their business. The reagents would still be available *for other uses* by anyone. Sanova was a profit-making enterprise. Without an exclusive license, Sanova would not have taken on production of these kits and they would not have been available.

2. Restricted Use Agreements

➢ IRRI's Golden Rice Project

IRRI's Golden Rice Project provides an example of Restricted Use Agreements under which IRRI has acquired third party inputs with restrictions. These inputs (gene constructs, other proprietary materials and methods) will be incorporated into IRRI products. The Restricted Use Agreements (license or MTAs) affect the distribution of enhanced rice germplasm.

Golden rice is material produced by the introduction of transgenes into rice germplasm. These unique transgenes, and the methods by which transgenic (GMO) materials are produced, require the use of proprietary materials and methods, many of which are patented. IRRI and partner institutions can only obtain many of these intellectual assets from Syngenta. In addition, the inventors of the gene constructs and Syngenta have been instrumental in assembling a complete "package" of materials and methods that are necessary to produce "golden rice"[3]. Therefore institutions wishing to do this sort of research and produce such products must sign agreements with Syngenta that limit the distribution of Golden rice germplasm to "humanitarian" use.

According to the Golden Rice Project[4], the specific "humanitarian use" terms in these agreements include: 1) use in developing countries (low-income, food-deficit countries as defined by FAO); 2) resource-poor farmer use (earning less than US$10,000 per year from farming); 3) technology must be introduced into public germplasm (seed) only; 4) no surcharge may be charged for the technology (i.e. the seed may cost only as much as a seed without the trait); 5) national sales are allowed by such farmers (in this way urban needs can also be covered); and 6) reuse of harvested seed in the following planting season is allowed (the farmer is the owner of his seeds). (Additional terms of the license address biosafety issues, reach-through rights, etc.) These use restrictions are compatible with the CGIAR Vision in the countries where they can be made available.

Were these Restricted Use Agreements necessary for this project?

The third party biotechnology necessary for this project is proprietary and the use of the unique patented transgenes and methods are essential for the project to go forward. The terms of the licensing agreements will allow IRRI and its partners to move forward with this research and also to ensure that material will be available for distribution to poor farmers as well as other research institutions, particularly those that support the CGIAR Vision.

[3] http://www.goldenrice.org/Content1-Who/who2_history.html
[4] http://www.goldenrice.org/Content2-How/how9_IP.html

3. IP Applications

➢ ILRI's East Coast Fever (ECF) Vaccine Project

ILRI has made patent applications over inventions vaccines produced in the context of cooperative partnerships. The purpose of these patents was to retain the control over how these inventions were used and to be able to provide assurance to their partners that their partners' technology that incorporates ILRI's technology would be available for potential exclusive uses in non-East Coast Fever fields. Such other fields might include other protozoan infectious diseases both animal and human-related and human health situations such as cancers of the immune system such as lymphomas. ILRI has been working towards the development of vaccines to protect cattle against East Coast Fever since the early 1980's. ILRI researchers and their partners, taking a molecular approach, have employed various methods to identify the precise antigens recognized by an animal's immune system. These antigens have then been incorporated into "delivery agents" to prepare vaccines. The vaccines are then administered to animals. The efficacy of the vaccines are tested by challenging vaccinated animals with infectious doses of *Theileria parva*, the causal agent of East Coast Fever (ECF) disease. Obviously, this is a complex disease and developing an effective vaccine, administering the vaccine, and testing the efficacy of the entire vaccination process requires many different research competencies as well as many intellectual assets.

For this molecular approach, ILRI has worked in partnership with many institutions, both public and private. There have been roughly two phases of research: initial antigens were identified in the late 1980's and a US Patent was awarded to ILRI in 1993[5]. A second collaborative phase had its beginnings in 1998 and eventually this project involved a new set of partners, both a private pharmaceutical company, Merial Ltd., and public entities. Partners in such a project would need to have a "comfort level" that attribution as well as good "stewardship" of intellectual assets would be the order of the day. Therefore, in addition to confidentiality agreements, research agreements, etc., ILRI and the other partners needed to negotiate agreements with terms that covered intellectual assets. In this project agreements address IP with terms according to which: 1) "public" antigen discovery IP (e.g. primarily ILRI-identified antigens) would be covered through patent rights held by public partners and 2) any vaccine product IP (e.g. the vaccine and delivery system) would be held by Merial. Merial agreed to provide financial support for the prosecution of ILRI patent applications.

ILRI moved to protect some of its intellectual assets generated in this research through patent applications and a filing was made in 2003[6]. This collaboration ended in 2008, as the project was unable to develop an efficacious vaccine according to the project timeline developed by the project[7]. In 2010, ILRI decided to abandon the ECF Patents based on a review of ILRI's vaccine research and development strategy. It was felt not necessary to continue with ILRI's ECF patent portfolio as all the ECF antigen sequences and their potential use in vaccine development have been published and the information protected by the patents is in the public domain and can therefore not be patented by third parties. ILRI also decided going forward not to undertake patenting of new antigens from future vaccine research, but to overcome potential IP restrictions through publication.

Was it necessary to file for patent protection in this project to meet its objectives for developing a vaccine that could be distributed "at-cost" to poor cattle farmers in East Africa?

No one institution can possibly have all of the types of expertise and facilities for the research that is required for such a project. To move forward, ILRI had to attract the collaboration of leading research Centers in vaccine development as well as of institutions that could assist in testing "candidate" vaccines. On its own, the identification of antigens would not allow the production of a vaccine that

[5] US Patent# 5,273,744
[6] WO 2005030802
[7] For additional information on this project, see, Spielman, 2008 www.nap.edu/html/12541/12541_casestudies_app.pdf)

farmers could use. And vaccine development, especially research that utilizes "cutting-edge" technology, is a very, very competitive area, both for scientific recognition and for profit.

Patent protection provides attribution to inventors and conditions enabling the private sector to make a profit. In addition, patent protection also serves the purpose of disclosure of research results in addition to publication of scientific reports in high-quality, peer-reviewed scientific journals. The written description section of a patent/patent application would describe, in detail, the structure of any antigens that were identified and how they were identified. Similarly, vaccine inventions would need to be described in a manner that those outside of the patent-granting territory could make and use the invention[8]. Also by making a patent application, ILRI was also engaging in "defensive patenting", a term used to describe the seeking of patent rights that would prevent another entity from getting patent protection over a similar invention. This happens because patent rights are only awarded to new/novel inventions that are non-obvious. Any public disclosure, particularly a prior patent application, can be used by a patent examiner to reject claims on the basis of prior disclosure (usually called 'prior art' in patent lingo). In the ILRI patent application situation[9], for example, Merial also filed a patent application[10] covering DNA constructs to be used as vaccines that incorporated the genes described in the ILRI patent application. The preliminary examination report from the European Patent Office cited the ILRI patent as blocking to certain claims in the Merial patent and thus these Merial claims would be rejected in the examination process.

What might have happened if ILRI had not filed their patent application?

If ILRI had not filed this patent application there is a high probability that the Merial claims would have been allowed during the patent prosecution process and then Merial would have been the sole owner of the rights over ILRI's research results.

[8] Patent rights are territorial. If an entity wishes to use, make, or sell an invention covered by patent rights, permission must be sought from the patent rights holder. In addition, patented inventions could not be made elsewhere and then imported into the territory without infringing the rights of the patent holder unless permission was given be the owner.
[9] WO 2005030802
[10] WO 2006101810